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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,883	09/15/2006	Siegfried Ansorge	P29678	4705

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EXAMINER	
SZNAIDMAN, MARCOS L	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/575,883	ANSORGE ET AL.	
	Examiner	Art Unit	
	MARCOS SZNAIDMAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *112-131* is/are pending in the application.

4a) Of the above claim(s) *114,117 and 124-131* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *112,115 and 118-123* is/are rejected.

7)☐ Claim(s) *113 and 116* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 page / 06/03/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's reply filed on June 3, 2009.

Status of Claims

Cancellation of claims 93-111 and addition of new claims 112-131 is acknowledged.

Claims 112-131 are currently pending and are the subject of this Office Action.

Newly submitted claims 124-131 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 112-123 recite a pharmaceutical or cosmetic composition, while claims 124-131, recite a method of inhibiting an activity of an enzyme with the above composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 124-131 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The following species are currently under examination: compound D3.008 (which is free of prior art), elected by applicant in the reply filed on May 13, 2008. Since the elected species is free of prior art, examination was expanded to the following species: Zaleplon (CAS# 151319-34-5 for the neutral form and 899446-93-6 for the HCl form). Due to Applicant's amendments, the species Lupanine (CAS # 550-90-3), selected by

the Examiner as the next species examined in an expanded search in the Office Action dated August 29, does no longer read on the instant claims.

The combined sets of claims that read on one or both species, and as a consequence are under examination are: 112-113, and 115-116 and 118-123.

Claims 114 and 117 are withdrawn from consideration because it does not read on the elected invention and/or on any of the two species being examined.

Priority

The present application is a 371 of PCT/EP04/11645 filed on 10/15?2004.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not

Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (new Rejection necessitated by Amendment)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 112 , 115, 120 and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heydom (Expert Opinion on Investigational Drugs (2000) 9:841-858) in view of Oettel et. al. (US 2002/0065260, cited in prior office action).

Claims 112, 115 and 123 recite a pharmaceutical or cosmetic composition comprising at least one of a pharmaceutically acceptable carrier and a pharmaceutically or cosmetically acceptable adjuvant and at least one active ingredient selected from formula I (see claim 1).

For claims 112, 115 and 123, Heydom teaches a pharmaceutical composition comprising Zalepon (see figure 1 on page 842) which is encompassed by the general formula I of claim 1.

Heydom does not teach a pharmaceutically or cosmetically acceptable adjuvant. However, Oettel teaches that adjuvants are common use in the pharmaceutical industry (see paragraph [0043], lines 10 and 11).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have a pharmaceutical composition of Zalepon and a pharmaceutically acceptable carrier as taught by Heydom and further add an adjuvant as taught by

Oettel, with the motivation of obtaining a better formulation of Zalepon, thus resulting in the practice of claims 112, 115 and 123 with a reasonable expectation of success.

The statement in claim 115: "suitable for use in a method of inhibiting an activity of at least one enzyme selected from dipeptidyl peptidase IV and analogous enzymes in a subject in need thereof" and the statement in claim 123: "wherein the composition is suitable for use as a cosmetic composition", are considered an intended uses and do not add any new limitation to the claims. Catalina Mktg. Int'l, Inc. V. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (fed. Cir. 2002). "The recitation of a new intended use for an old product does not make a claim to that old product patentable." In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Claim 120 further limits claim 112, wherein the composition is suitable for at least one of oral, transdermal, etc., administration.

For claim 120, Heydom further teaches that Zalepon can be administered orally (see page 847, section 3.1, first sentence).

Claim 118 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heydom (Expert Opinion on Investigational Drugs (2000) 9:841-858) in view of Oettel et. al. (US 2002/0065260, cited in prior office action), as applied for claims 112, 115, 120 and 123 above, further in view of Ding et. al. (US 6,120,536).

Claim 118 further limits claim 112, wherein the composition is comprised in a coating of a stent.

Heydom and Oettel teach all the limitations of claim 118, except for the composition being comprised in a coating of a stent. However, Ding teaches that coating stents with pharmaceutical agents is common practice in the pharmaceutical industry (see column 1, last paragraph and column 2, first and second paragraphs).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 112 comprised in a coating of a stent as taught by Ding, with the motivation of having a better delivery of the active ingredient Zalepon), Thus resulting in the practice of claim 118 with a reasonable expectation of success.

Claim 119 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heydom (Expert Opinion on Investigational Drugs (2000) 9:841-858) in view of Oettel et. al. (US 2002/0065260, cited in prior office action), as applied for claims 112 , 115, 120 and 123 above, further in view of Papathanassiu (US 6,528,489, cited in prior Office Action).

Claim 119 further limits claim 112, wherein the composition is suitable for topical administration.

Heydom and Oettel teach all the limitations of claim 1119, except for being suitable for topical administration. However, Papathanassiu teaches that topical administration of active ingredients is common practice in the pharmaceutical industry (see column 5, second paragraph).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 112 suitable for topical administration as taught by Papathanassiu, with the motivation of having a better form of administration, thus resulting in the practice of claim 119 with a reasonable expectation of success.

Claim 121 further limits claim 112, wherein the composition is present as a cream an ointment, a paste, and a gel.

Heydom and Oettel teach all the limitations of claim 121, except for the composition being a cream, an ointment, a paste or a gel. However, Papathanassiu teaches that creams, ointments, pastes and gels are common formulations of active ingredients in the pharmaceutical industry (see column 5, second paragraph).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 112 in a form of a cream, ointment, past or gel as taught by Papathanassiu, with the motivation of having a better formulation for the active ingredient, thus resulting in the practice of claim 1121 with a reasonable expectation of success..

Claim 122 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heydom (Expert Opinion on Investigational Drugs (2000) 9:841-858) in view of Oettel et. al. (US 2002/0065260) as applied to claims 112, 115, 120 and 123 above, and further in view of Lintner (US 6,620,419, cited in prior Office Action).

Claim 122 further limits claim 112, wherein the composition is present in combination with at least one of a depot matrix, a hydrocolloid dressing, a plaster, a micro-sponge and a prepolymer.

Heydom and Oettel teach all the limitations of claim 122, except for being present in combination with at least one of a depot matrix, a hydrocolloid dressing, a plaster, a micro-sponge and a prepolymer. However, Lintner teaches that micro-sponges are common use in the pharmaceutical industry (see column 6, line 44).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 112 present in a micro-sponge as taught by Lintner, with the motivation of better delivering the active ingredient, thus resulting in the practice of claim 122 with a reasonable expectation of success.

Claim Objections

Claims 113 and 116 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The compound of claims 113 and 116 is free of prior art.

Withdrawn Rejections and/or Objections

Claims rejected under 35 USC 112, first paragraph (written description).

Due to Applicant's cancellation of claims 105, 108 and 111, the written description rejection is now moot.

Rejection under 35 USC 112, first paragraph (written description) is withdrawn.

Claims rejected under 35 USC 102 (b)

Due to Applicant's cancellation of claim 93, the 102 rejection is now moot.

Rejection under 35 USC 102(b) is withdrawn.

Claims rejected under 35 USC 103 (a)

Due to Applicant's cancellation of claims 93, and 105-111, the 103 (a) rejection is now moot.

Rejection under 35 USC 103 (a) is withdrawn.

Claims rejected under nonstatutory Double Patenting.

Due to applicant's amendment of the claims the Double Patenting rejections are now moot.

Rejection under nonstatutory Double Patenting is withdrawn.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
July 16, 2009

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612